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09/615,305	07/13/2000	Wolfgang Meier	BioCure 101	4801

7590

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 20040526

Application Number: 09/615,305  
Filing Date: July 13, 2000  
Appellant(s): MEIER ET AL.

**MAILED**  
**JUN 04 2004**  
**GROUP**

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Collen A. Beard  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3-18-2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Upon consideration, the 112, second paragraph rejection of claim 17 is withdrawn.

**(7) *Grouping of Claims***

The claims stand or fall together.

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

6,008184	PLUYTER	12-1999
5,891,468	MARTIN	4-1999
WO 97/49387	SEARLE AND CO.	12-1997

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

1. Claims 1, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Pluyter (6,008,184).

Pluyter discloses vesicles containing triblock polymers A-B-A wherein A is water-soluble polymer and B is water insoluble polymer (note col. 2, line 25 et seq., col. 5, lines 51-55, col. 14, lines 61-62).

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant argues that Pluyter does not teach membranes formed from amphiphilic copolymers, but rather teaches lamellar vesicles which may have copolymers partially incorporated. This argument is not found to be persuasive since the membranes are still made of the copolymers along with the other vesicle forming structures and instant claim language does not require that the vesicle membranes be

Art Unit: 1615

totally made from the copolymers. Appellant argues that there is no indication in Pluyter that the vesicles are hollow. Appellant points out to col. 1, lines 26-29 in Pluyter where vesicles are described as having an "onion-like configuration of ---concentric bilayers of molecules of fabric softening materials with entrapped water or electrolyte solution, the so-called aqueous phase" in support. This argument is not found to be persuasive. The examiner respectfully directs board's attention to appellant's own statements in the response to the 112, first paragraph rejection in the final rejection dated 7-28-2003 (paragraph bridging pages 2 and 3). Appellant's statement is as follows.

" An interior void means that the vesicle is hollow. The term "hollow" is defined on the online Meriam Webster dictionary (see Exhibit A) as "having a cavity within",

such as "hollow tree". Even though the interior of the tree is filled with air, it is still considered to be hollow. The vesicles of the invention do not have polymer in the

interior, thus they have an interior void, i.e. they are hollow (see Exhibit B for the definition of the term 'void' from the online Merriam Webster dictionary). They most

likely are filled with fluid if they are in a liquid environment, but they are still 'hollow' as the term commonly used."

This statement indicates that according to appellant, even if the interior of the vesicle is filled with either air or fluid it is considered as 'hollow' as long as they do not have polymer in the interior and the interior is not solid. Thus, Pluyter which discloses vesicles with entrapped water or electrolyte solution meets the requirements of instant claims.

2. Claims 1, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin (5,891,468).

Art Unit: 1615

Martin discloses liposomes (vesicular nanocapsules) made from triblock polymers. The liposomes carry targeting ligand such as folic acid (note the abstract, figures, columns 7-11, examples and claims).

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant once again argues that Martin does not disclose vesicles having membranes formed from amphiphilic copolymers as required by the claims and that the vesicles taught by Martin are liposomes having diblock copolymer attached to thereto. This argument is not found to be persuasive for the following reasons. First of all, instant claim language does not exclude liposomes (liposomes are vesicles) and other material contributing to the membrane as in Martin. The copolymers in Martin are part of the membranes.

#### *Claim Rejections - 35 USC § 103*

3. Claims 1, 3-6, 9-14, 16-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/49387 (Wooley) by itself or in combination with Martin cited above.

WO as discussed before, discloses nanoparticles containing vesicles. The vesicles are made of amphiphilic triblock copolymers. Either the core domain or the shell domain is hydrophilic. The polymerization is achieved photo chemically. The nanoparticles further containing a pharmaceutically active agent (note the abstract, pages 4-5. 64, 72, 87, and claims). WO, although does not provide specific examples of the preparation of the nanoparticles having the pharmaceutical agents within, or

Art Unit: 1615

particles with triblock polymers, it is suggestive of encapsulation of active agents in the core domain. Therefore, it is deemed obvious to one of ordinary skill in the art to encapsulate the active agents in the core or prepare the nanoparticles from triblock polymer since WO provides guidance for such a preparation of particles. One of ordinary skill in the art would be motivated further to use triblock polymers in the preparation of the nanoparticles from the guidance also provided by Martin. The use of targeting ligand in WO is deemed obvious to one of ordinary skill in the art since these ligands would target the composition to the desired sites in the body. One of ordinary skill in the art would be motivated further to include a targeting ligand such as folic acid in WO since Martin shows its routine use in vesicle preparations containing triblock polymers.

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant pointing out to page 12, lines 5-14 and page 69, lines 4-25 and argues that globular particles taught by Wooley are micelles wherein the outermost domain is cross-linked and that micelles are not hollow. The examiner respectfully points out to page 13, line 25 of WO where micelle definition includes vesicles and therefore, the core is hollow. Appellant's arguments are based on the lack of teachings in WO of hollow core in the particles (based on the exhibits D-F) are also not persuasive for the following additional reasons. The examiner's reasoning is as follows. In WO 97, as pointed out before, the inventors teach that the central core need not be cross-linked and suggest that the active agent can be in the interior core in a dissolved state or in the form of a fine dispersion meaning that there are spaces in the core for the active agents

Art Unit: 1615

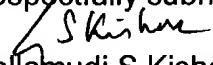
(see page 86). Based on this, one can interpret that what is discussed in exhibits D and E is the achievement by the inventors of WO to make the center core totally empty as a cage structure whereas the particles in WO are only partially empty if they are not cross-linked. If the core in WO is totally solid, the inventors would not have discussed the encapsulation of the active agent either in the solubilized state or as a dispersion since there will not be space for the active agent. In response, appellant argues that the term, 'dissolved' does not mean that the interior domain is empty or contains a liquid. This argument is not found to be persuasive. First of all, it is unclear as to why one would use the expression, 'dissolved' if a solvent is not involved. Even assuming that appellant is correct in that interpretation, the presence of a solvent for the active agent in the central core is very clear from WO's teachings on lines 12-23 of page 86. As pointed out above, since appellant's own definition of the term, 'hollow' means it can be filled with a liquid, WO's vesicles are hollow. Appellant's arguments that Martin teaches liposomes made of lipids to which triblock polymers can be added to increase the fusogenicity have been addressed above. Furthermore, the reason for which the triblock polymers are added in Martin need not be the same as appellant's. Appellant arguments that Wooley teaches micelles and Martin teaches liposomes and therefore, there is no motivation to combine are not persuasive since as pointed out above, Wooley's definition of micelles includes vesicles and liposomes are vesicular preparations.



Art Unit: 1615

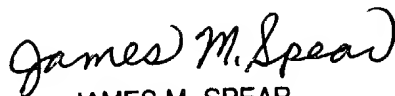
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


  
Gollamudi S Kishore, PhD  
Primary Examiner  
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GSK  
May 26, 2004

Conferees  
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